

K1008/20399



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

Applicants : Douglas G. Evans and John E. Nash
Serial No. : 09/369,107
Filed : August 5, 1999
For : TRANSMYOCARDIAL
REVASCULARIZATION SYSTEM AND
METHOD OF USE
Group Art Unit : 3731
Examiner : K. Truong

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §1.97(b)(3)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants request that the following documents be made of record in this
patent application:

U.S. PATENTS:

U.S. Patent No. 4,839,215

U.S. Patent No. 4,900,303

U.S. Patent No. 5,840,059

U.S. Patent No. 5,878,751

U.S. Patent No. 5,879,713

U.S. Patent No. 5,893,840

U.S. Patent No. 5,904,670

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U.S. Patent No. 5,935,119

U.S. Patent No. 5,997,525

FOREIGN PATENTS

International Publication No. WO 99/22655

International Publication No. WO 99/22658

International Publication No. WO 99/27985

International Publication No. WO 99/44523

International Publication No. WO 99/44524

ARTICLES

Basic Fibroblast Growth Factor in a Porcine Model of Chronic Myocardial Ischemia: A Comparison of Angiographic, Echocardiographic and Coronary Flow Parameters. Lopez et al., the Journal of Pharmacology and Experimental Therapeutics, Vol. 282, No. 1, pgs. 385-390, 1997.

Basic FGF Enhances Endothelium-Dependent Relaxation of the Collateral-Perfused Coronary Microcirculation. Sellke et al., The American Physiological Society, 1994, pgs. H1303-H1311.

Attached is PTO Form 1449 listing the above documents. Also attached herewith is a copy of each of the documents listed.

The relevance of these documents will be set forth hereinafter.

1. U.S. Patent No. 4,900,303 (Lemelson) describes a dispensing catheter for delivering an implantable material to a select portion of the wall of a body duct, e.g., to retain the material at a select site while slowly dispensing a drug to the tissue at the site. One embodiment of the catheter includes a needle that is projected from the catheter head to inject fluid into tissue adjacent the catheter head. The patent describes that "a mixture of one or more medications per se or in microcapsule containers mixed with a biodegradable

organic or inorganic adhesive may also be coated on or impregnated throughout the cellular material to be disposed as described from the instrument.” Another embodiment sprays liquid medications into cells of the wall of the body duct using a pressurized spray or stream.

2. U.S. Patent No. 5,839,215 (Stirling et al.) discloses a cloth-like article made up of biocompatible particles or beads, e.g., PGA and PLA, which can act as carriers for growth factors.

3. U.S. Patent No. 5,840,059 (March et al.) discloses a lasing transmission catheter for creating channels and delivering therapeutic agents into the channels. A viscous carrier is used to retain an agent within a channel. Channel forming means, other than laser radiation transmitting means can be used such as thermal ablation means, radio-frequency ablation means, rotating tissue removal means, water jet removal means and ultrasonic ablation means. Growth factors, genes and other agents can also be delivered. Timed release using absorbable materials is also discussed.

4. U.S. Patent No. 5,878,751 (Hussein) discloses myocardial stents of various configurations arranged to be implanted into the myocardium.

5. U.S. Patent No. 5,879,713 (Roth et al.) discloses the delivery of various types of broactive materials, such as growth factors, etc., to the body of a living being via various types of carriers, e.g., microparticles, polymeric pavings or films. In one embodiment microparticles of VEGF are injected into atherosclerotic arteries of the lower limbs to induce the creation of collateral circulation.

6. U.S. Patent No. 5,893,840 (Hull et al.) discloses a balloon catheter for introduction into a blood vessel or lumen. The balloon includes microcapsules containing a drug, (e.g., antiplatelets, antithrombogenics, growth factors, etc.) which may be useful to treat the lumen on the outer surface of the balloon, so that upon inflation of the balloon the drug is brought into contact with the lumen wall.

7. U.S. Patent No. 5,904,670 (Schreiner) discloses catheters for guiding drugs into a blood vessel or other lumen. The catheter includes plural deployable resilient grooved delivery members for carrying the drug into the vessel wall.

8. U.S. Patent No. 5,935,119 (Guy) discloses a perfusion stent arranged to be inserted into a TMR channel in the wall of the heart.

9. U.S. Patent No. 5,997,525 (March et al.) discloses a laser transmission catheter for creating TMR channels and delivering therapeutic agents therein.

10. International Application WO 99/22655 discloses various systems for effecting TMR using inserts, which may be resorbable and may include growth factors.

11. International Application WO 99/44523 describes a Percutaneous Myocardial Revascularization (PMR) device and method that relates to creating a crater wound in the myocardium to result in a healing response. The document mentions that “the collateral damage is preferably induced by directing pressurized saline, contrast media, drug or combination into the crater site through the endocardium and into the myocardium.” Also, it states “Once the endocardium is perforated, pressure from infused fluid can rupture the myocardial vessels without further ablation or removal of tissue. In order to retain contrast media within the crater for an extended period of time, a mixture of Loctite

adhesive can be radiopaque loaded with platinum or other biocompatible radiopaque material.

12. International Application WO 99/44524 also discloses a Percutaneous Myocardial Revascularization (PMR) device and method that relates to creating multiple holes in a heart chamber wall simultaneously. One embodiment has a high-pressure fluid jet cutting means. It is described that one of the embodiments has a lumen that "continues through the electrode such that contrast medium, growth factor or other drugs can be delivered to the wound created by the PMR procedure.

13. International Application WO 99/22658 also discloses a Percutaneous Myocardial Revascularization (PMR) device and method that relates to creating channels in the myocardium leading from healthy tissue to hibernating tissue. In one embodiment, a cutting tip injects radiopaque material in conjunction with the cutting of a channel. In this embodiment, as each channel is formed a temporary radiopaque marker is left, creating a pattern of radiopaque markers viewable fluoroscopically. A catheter is disclosed with a hypodermic needle that can infuse contrast media, growth factor or other drug into the wall of the myocardium. There is also described an abrasive burr that can be used to form a crater in the wall.

14. International Application WO 99/27985 discloses a catheter to deliver a drug, growth factor, gene therapy materials, radioactive fluid, cancer treatment, clot dissolution agent, or other desired material. The material can be injected by high pressure, at high velocity, to mechanically break up clots.

15. The article "Basic Fibroblast Growth Factor In Porcine Model . . ." discusses perivascular administration of bFGF (basis fibroblast growth factor) via microspheres into porcine models.

16. The article "Basis FGF enhances endothelium . . ." also discusses administration of bFGF via microspheres placed around selected coronary arteries in porcine models.

An Office Action restricting the invention has been received in this application and a response to the restriction requirement has been filed. As far as the undersigned is aware, there has been no Office Action on the merits.

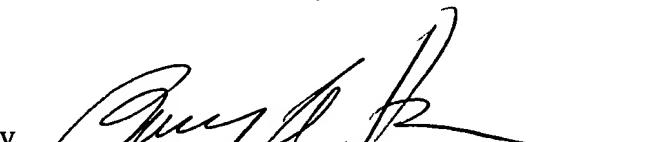
In the event that a fee is required for the filing of this Information Disclosure Statement, please charge our deposit account No. 03-0075 in the amount of Two-Hundred, Forty Dollars (\$240.00) in accordance with 1.17(p). A duplicate of this Information Disclosure Statement is enclosed.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

March 15, 2000

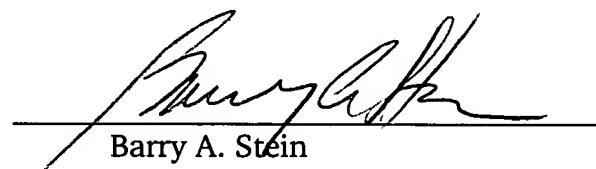
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CERTIFICATE OF MAILING

I hereby certify that the foregoing SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR §1.97(b)(3) re Application Serial No. 09/369,107, PTO Form 1449 and attached references are being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, this 13th day of March, 2000.



Barry A. Stein